DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 13, 2014

Unimicro Medical Systems (ShenZhen) Company, Ltd.
% Mr. Long Yang
Shenzhen Hlongmed Biotech Company, Ltd.
R15-08, East Building, Yihai Plaza, Chuangye Road, Nanshan District
Shenzhen, Guangdong 518054
People's Republic of China

Re: K141593
Trade/Device Name: Unimicro Disposable Retrieval Endo-Pouch,
models: Auto Retrieval Endo-Pouch, Endo-Pouch With Introducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 17, 2014
Received: October 23, 2014

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141593

Device Name
Unimicro Disposable Retrieval Endo-Pouch, models: Auto Retrieval Endo-Pouch， Endo-Pouch With Introducer

Indications for Use *(Describe)*
The Unimicro Disposable Retrieval Endo-Pouch is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Unimicro Medical Systems (ShenZhen) Co., Ltd.

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K141593

1. Submitter information:

Manufacturer Name: Unimicro Medical Systems (ShenZhen) Co.,Ltd.
Address: 2/F, Bldg 31, The 3rd Industrial Area, Mashantou, Gongming Street, Guangming New District, ShenZhen City,Guangdong Province, China
Tel : 0086-755-27111581
Fax : 0086-755-27111580
Establishment Registration Number:3010806467

2. Contact person:

Long Yang (COO)
Shenzhen Hlongmed Biotech Co., Ltd.
R1508, East Building, Yihai Plaza, Chuangye Road, Nanshan District,Shenzhen, P.R. China
Tel: 0086-755-86664986
Fax: 0086-755-86664933
E-mail: yanglong@hlongmed.com

3. Device Information:

Trade Name: Unimicro Disposable Retrieval Endo-Pouch
Model: Auto Retrieval Endo-Pouch, Endo-Pouch With Introducer
Common Name: Tissue Bags
Regulatory Class: II

Classification Name	Product Code	Regulation Number
Laparoscope, General & Plastic Surgery	GCJ	876.1500

4. Predicative Device

Table 1: Predicative Device Information

Device Name	Common Name	Manufacturer	Classification and Code	Classification regulation	510(k) number
Unimax Specimen Retrieval System	Tissue Bags	Unimax Medical Systems Inc.	Class Ⅱ, GCJ	21CFR 876.1500	K103510

5. Intended Use and Indications for Use of the subject device

The Unimicro Disposable Retrieval Endo-Pouch is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

6. Description

The Unimicro Disposable Retrieval Endo-Pouch is a sterile and single-use specimen container designed for use in retrieving specimens during endoscopic surgery. The Unimicro Disposable Retrieval Endo-Pouch is supplied in a dispending tube for ease of insertion through a standard 10,11or 12mm trocar sheath.

7. Non-clinical Testing

A series of preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Unimicro Disposable Retrieval Endo-Pouch. All the test results demonstrate the performance of Unimicro Disposable Retrieval Endo-Pouch meets the requirements of its predefined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Non-clinical Testing is as safe and effective as the predicate devices.

8. Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

9. Substantial Equivalence Determination

The Unimicro Disposable Retrieval Endo-Pouch submitted in this 510(k) file is substantially equivalent in intended use, design, principles of operation, materials ,performance and sterilization to the cleared Unimax Specimen Retrieval System which is the subject of K103510.There are no difference between the Proposed Device and Predicate Device, see Table 2.

Table 2 : Comparison to Predicate Device

Item	Proposed Device	Predicate Device
Trade Name	Unimicro Disposable Retrieval Endo-Pouch	Unimax Specimen Retrieval System
510(K) Submitter	Unimicro Medical Systems (ShenZhen) Co.,Ltd.	Unimax Medical Systems Inc.
510(K) Number	----------	K103510
Classification regulation	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	Class Ⅱ, GCJ	Class Ⅱ, GCJ
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery
Indications for Use	Indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.	Indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.
Material	Various polymer Stainless	Various polymer Stainless

Specification	consists of a flexible polymer bag and an introducer structure that fits through a trocar port	consists of a flexible polymer bag and an introducer structure that fits through a trocar port
Biocompatibility	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-12 :2012	ISO 10993-1:2003 ISO 10993-5:2009 ISO 10993-10:2002 ISO 10993-12 :2007
Sterilization	EO Sterilized	EO Sterilized

10. Conclusion

After analyzing bench tests, it can be concluded that Unimicro Disposable Retrieval Endo-Pouch is as safe and effective as the predicate device.